

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 26-36 are pending with entry of this amendment. Claims 26, 30 and 34 are amended herein. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

Claim 26 is amended to remove an extraneous comma as requested by the Examiner. Claims 30, 34 and 36 are amended/added to address antecedent basis issues, thereby further clarifying the claimed invention. As such, the amendments are purely formal in nature. Applicant submits that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

Restriction Requirement.

Applicant acknowledges the vacation of the restriction requirement mailed May 13, 2003, per the telephonic interview held July 1, 2003 and the Interview Summary mailed July 7, 2003.

Specification Objections

Applicant has amended the specification to correct typographical errors and informalities, as helpful suggested by the Examiner. Applicant submits that no new matter has been added to the application by way of these amendments.

The Information Disclosure Statement.

Applicant notes that the Information Disclosure Statement (Form 1449) submitted on July 8, 2002, is a copy from related applications USSN 09/414,916 and USSN 08/336,724 as noted on page 3 of the IDS transmittal form, and from which the subject application claims priority. Per 37 CFR 1.98(d), copies of the publications need not be submitted again. As such, Applicant submits that the Examiner's allegation that the IDS submission was incomplete is INCORRECT, and respectfully request that the cited references (as submitted on July 8, 2002) be considered. For the convenience of the Examiner, copies of the references will follow in a separate transmittal (due to the number of publications being forwarded).

Applicant herewith submits a supplemental Information Disclosure Statement and accompanying Form 1449, providing references cited in a Japanese application corresponding to related patent USPN 5,811,653. Applicant respectfully requests that the references be considered and made of record by the Examiner.

35 U.S.C. §112, Second Paragraph.

Claims 26-35 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter that the Applicant regards as the invention. Applicant traverses the rejections as follows.

Claim 26 is not indefinite due to the use of standard punctuation

With respect to claim 26, Applicant submits that the claim is clear with respect to the fact that the adjective "plus strand" refers to an RNA-type component (the replication origin of line 3 or the replicase of lines 7 and 11). One of skill in the art would not find the claim unclear as to whether the term referred to RNA or DNA since both "plus strand" and "RNA" are used as adjectives preceding a

given noun (i.e., "origin" or "replicase") Applicant notes that series of adjectives are typically delineated by one or more commas (see, for example, *The Elements of Style*, by Edward Strunk, Jr.). However, in order to facilitate prosecution, Applicant has amended the relevant claims (i.e., to remove the comma). Applicant submits that claim 26 is not indefinite; as such, the rejection is improper and should be withdrawn.

Claim 26 is clear with respect to "replicating"

Claim 26 is also allegedly unclear with respect to "whether or not RNA replicase also participates in said 'replicating' step and as to what are components additional to the recombinant mRNA molecules and the replication origin." Applicant traverses since the rejection does not make sense and has no basis under the second paragraph of 35 USC §112.

Claim 26 includes the step of replicating the recombinant mRNAs with the plus sense RNA viral replicase, thereby producing additional replicon components. One of skill in the art would be familiar with the rules of grammar and punctuation, and would recognize that the replicase is the "noun" performing the "verb," the act of replicating. As such, Applicant submits that the rejection is inappropriate; grammar and punctuation issues are not a basis for making a §112 second paragraph rejection.

Enablement is not a basis for rejection under §112, second paragraph

With respect to claim 29, Applicant traverses the Examiner's allegation that the claim recitation does not make apparent as to *how* to produce mRNA via self-cleavage. Rejection of a claim using the second paragraph of §112 should address whether the claim particularly points out and distinctly claims the subject matter which the Applicant regards as his invention. Claim 29 is drawn to a method in which producing the subgenomic mRNA further comprises self-cleaving the mRNA, the meaning of which is self explanatory. Self-cleavage of RNA has been known in the art since Tom Cech's work in 1984, and would readily be understood by one of skill in the art. As such, an argument cannot be made that the claim is indefinite. Furthermore, the question of "how" a step is achieved is not a basis for making a rejection under §112, second paragraph. If the Examiner intended to make an enablement rejection under the first paragraph of §112, he should address the issue in an appropriate manner, e.g., by providing an analysis (under the "Forman Factors") that establishes the appropriate consideration for enablement.

Applicant submits that claim 29 is not indefinite. Since the Examiner has not provided a basis in law for the rejection of claim 29 under the second paragraph of §112, the rejection is improper and must be withdrawn.

Claim 30 is not indefinite

While Applicant does not agree that the claim language is indefinite, claim 30 has been amended to further clarify the claimed invention. Applicant respectfully requests that the rejection be withdrawn.

Claim 34 is not indefinite with respect to antecedent basis

Claim 34 has been rejected by the Office as indefinite for allegedly being unclear with respect to "how many sequences there are encoding the functional movement protein." Applicant assumes that the Examiner is concerned that there may be some confusion with respect to antecedent basis between the terms "at least one sequence [as encoded by the replicon]" and "a sequence encoding the functional protein." While Applicant does not agree that the claim as presented was unclear, in order to facilitate prosecution of the subject application, claim 34 has been amended, and new claim 36 has been added, to address the Examiner's concerns. In light of the amended claim, Applicant submits that the rejection with respect to number of sequences is irrelevant and respectfully request that the rejection be withdrawn.

35 U.S.C. §112, First Paragraph.

Claim 29 was rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the Applicant, at the time the application was filed, had possession of the claimed invention. Applicant traverses the rejection.

The subject matter of claim 29 is described in the specification

Written description under 35 U.S.C. §112, first paragraph requires that the inventor has possession of the claimed invention at the time of filing. Claim 29 is drawn to a method of expressing a foreign gene product, in which the subgenomic mRNA is produced by self-cleaving the mRNA. The Office Action alleges that Applicant is not in possession of a method involving a self-cleaving mRNA "because the instant specification provides insufficient description and/or guidance as to how the self-cleavage mechanism has an input on the claimed method."

The rejection is incorrect. It is self-evident how the self-cleavage mechanism of claim 29 has an input on the claimed invention: as a dependent claim, claim 29 describes an embodiment of the claimed method of producing foreign gene products in which the RNA undergoes a self-cleavage process. Support for self-cleavage of RNA transcripts can be found in the specification at, for example, page 12, lines 13-15 and page 15, lines 18-26. Furthermore, knowledge regarding nucleic acid sequences that can mediate self-cleavage are well known in the art (e.g., starting with Tom Cech's seminal work in 1984). Applicant submits that one of skill in the art would readily understand how to produce subgenomic mRNA via self-cleavage as applied to the subject invention, in light of the subject application. Accordingly it is clear that Applicant had possession of the claimed invention at the time of filing. The rejection is improper and must be withdrawn.

"Importance" is not a basis for making a §112 first paragraph rejection

The Office Action also alleges that the specification "fails to describe additional representative example or any other evidence of record which shows the self-cleavage is particularly important or useful in plant plus-strand RNA virus-based over expression of foreign genes encoding antisense polynucleotide or ribosomal RNA, or regulatory enzymes, or structural, regulatory, and therapeutic proteins."

The first paragraph of §112 does not require that a particular claim be "important." The question of the "importance" of a dependent claim is not a basis for making a rejection under §112, first paragraph. If the Examiner intended to make a utility rejection under 35 USC §§101 or 112, he should address the issue following the Office guidelines regarding utility rejections, which the present rejection manifestly fails to do. Applicant further notes that the utility of the claimed invention is perfectly clear: the usefulness of self-cleavage as a part of the process of providing a nucleic acid construct is readily apparent, particularly in light if the number of publications and patents issued in this field.

Furthermore, the statement made by the Examiner makes no logical sense. Applicant does not understand what is meant by "additional representative example." No first representative example is delineated in the Office Action. Moreover, representative examples are not a requirement of patentability.

Since there is no basis under the first paragraph of §112 to reject the "importance" of claim 29, nor has a *prima facie* case for alleged lack of utility been made under the guidelines established by the Office, the rejection is obviously improper and must be withdrawn.

Limitations from the specification cannot be read into the claim to form a basis for rejection

The Office Action also alleges that "one of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus" and cites

University of California v. Eli Lilly and Co. (43 USPQ2d 1398). Applicant traverses since the rejection does not make sense and has no basis under the first paragraph of 35 USC §112.

As noted above, claim 29 is drawn to a method of expressing a foreign gene product, in which the step of producing the subgenomic mRNA further comprises self-cleaving the mRNA. The rejection does not identify the species in question. Applicant requests that the Examiner provide clarification regarding what "species" and "genus" are being alleged in the rejection of claim 29. As one possible explanation for the rejection based upon an inadequate number of "representative species," Applicant hypothesizes that the Examiner is reading additional limitations from the specification and/or claim 31 (regarding various embodiments of the "foreign gene product") into claim 29.

The Office Action repeatedly refers to "plant plus-strand RNA virus-based over expression of foreign genes encoding antisense polynucleotide or ribosomal RNA, or regulatory enzymes, or structural, regulatory, and therapeutic proteins." However, neither dependent claim 29 nor independent claim 26 are limited to foreign gene products encoding antisense polynucleotides, ribosomal RNA, regulatory enzymes, structural proteins, regulatory proteins, and/or therapeutic proteins. Applicant wishes to remind the Examiner that specific embodiments appearing in a specification or in a dependent claim should not be read into the other claims when the claim language is broader than such embodiments (Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.; 34 F.3d 1048, 1054, 32 USPQ2d 1017, 1021 Fed. Cir. 1994). Also see page 1105, third column, of the Revised Interim Guidelines (the "Written Description Requirement" cited by the Examiner).

Since limitations from the specification cannot be read into the claims as a basis for rejection under the first paragraph of §112 (or any other portion of 35 USC), the rejection is improper and must be withdrawn.

Applicant submits that a) the specification does provide sufficient description and guidance with respect to the claimed self-cleavage mechanism. Nothing in the rejection actually addresses the claimed invention. Accordingly, the rejection entirely fails to make out a *prima facie* basis for a rejection.

Obviousness-Type Double Patenting.

Claims 26-28 and 30-35 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 10-12 and claims 16-20 of USPN 5,811,653 ("Viral Amplification of recombinant mRNA in Transgenic Plants" to Turpen).

Claims 26-28 and 30-35 were also rejected under the judicially-created doctrine of obviousness-type double patenting over claims 10-12 of USPN 5,889,191 ("Viral Amplification of recombinant mRNA in Transgenic Plants" to Turpen).

Claims 26-28 and 30-35 were also rejected under the judicially-created doctrine of obviousness-type double patenting over claims 13-19 of USPN 6,462,255 ("Viral Amplification of recombinant mRNA in Transgenic Plants" to Turpen).

Claims 26-28 and 30-35 were also rejected under the judicially-created doctrine of obviousness-type double patenting over claims 11-16 of USPN 5,965,794 ("Viral Amplification of recombinant mRNA in Transgenic Plants" to Turpen).

Applicant will supply Terminal Disclaimers upon notification that the pending claims are otherwise allowable.

Appl. No. 09/930,329
Amdt. Dated December 19, 2003
Reply to Office action of August 22, 2003


CONCLUSION

In view of the foregoing, Applicant believes all claims currently pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, **a telephone interview with the Examiner is hereby requested**. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,



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Attachments:

- 1) A petition to extend the period of response for one month;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet;
- 4) Form 1449 and accompanying Information Disclosure Statement; and,
- 5) A receipt indication postcard.

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